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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,004	09/25/2003	Kazuhiro Aikawa	Q77153	6236

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EXAMINER
KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
01/12/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/670,004	AIKAWA, KAZUHIRO	
	Examiner	Art Unit	
	Gollamudi S. Kishore, Ph.D	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 4-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 4-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12-10-08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The RCE dated 11-17-08 is acknowledged.

Claims included in the prosecution are 1 and 4-6.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1 and 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over in combination with EP 0583 665, Aikawa (7,101,532) or Kitaguchi (7,008,614) or Schmidt (6,077,529), Mjalli (7,087,632) individually or in combination.

2. Claims 1 and 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0583 665 cited above in view of Aikawa (7,101,532) or Kitaguchi (7,008,614) or Schmidt (6,077,529) individually or in combination.

EP as discussed before teaches liposomes containing PC and PS in 1:1 molar ratio. The benzimidazole however, is added to the medium containing the liposomes. According to EP the benzimidazole derivatives are for the treatment of hyperlipidemia and arteriosclerosis.

Aikawa, and Kitaguchi while disclosing liposomal compositions for radiography of a vascular disease (atherosclerosis) teach that liposomes are selectively taken up by vascular smooth muscle cells and macrophages. The liposomes contain PC and PS in

1:1 molar ratio and the hydrophobic active agent is in the membrane (abstract, Examples 5, 68 and 9 of Aikawa; abstract, Examples 4, 5 and 8 of Kitaguchi).

Schmidt discloses that liposomes are useful in handling arteriosclerosis. The phospholipids, which could be used in making the liposomes, include PC and PS (abstract, col. 5, lines 24-34 and claim 4).

Mijalli discloses liposomal formulations containing benzimidazoles for the treatment of atherosclerosis (abstract, col. 2, line 56, col. 37, lines 44-50 and claims). Mijalli however, does not specifically teach liposomes containing both phosphatidylcholine and PS. Mijalli just teaches that liposomes can bye made from a variety of phospholipids on col. 37, lines 44-50).

Assuming that the benzimidazole derivatives of EP are not associated with the liposomal membrane: it would have been obvious to one of ordinary skill in the art to encapsulate or associate the benzimidazole derivatives of EP in liposomes since the references of Kitaguchi, and Aikawa each teach that the liposomes are selectively taken up by vascular smooth muscle cells and macrophages and since the reference of Schmidt teaches that liposomes can be used in handling atherosclerosis. One of ordinary skill in the art would be motivated to use liposomes as delivery vehicles with a reasonable expectation of success since Mujalli who teaches the use of benzimidazole derivatives for atherosclerosis is suggestive of the use of liposomes as delivery vehicles.

3. Claims 1 and 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aikawa (5,387,600) of record in view of Aikawa (7,101,532) or Kitaguchi (7,008,614) or Schmidt (6,077,529), Mjalli (7,087,632) individually or in combination.

Aikawa (600) teaches that benzimidazole derivatives for the treatment of atherosclerosis (abstract and claims). What is lacking in Aikawa is the use of liposomes as the carriers.

Mijalli discloses liposomal formulations containing benzimidazoles for the treatment of atherosclerosis (abstract, col. 2, line 56, col. 37, lines 44-50 and claims). Mijalli however, does not specifically teach liposomes containing both phosphatidylcholine and PS. Mijalli just teaches that liposomes can bye made from a variety of phospholipids on col. 37, lines 44-50).

Aikawa, and Kitaguchi while disclosing liposomal compositions for radiography of a vascular disease (atherosclerosis) teach that liposomes are selectively taken up by vascular smooth muscle cells and macrophages. The liposomes contain PC and PS in 1:1 molar ratio (abstract, Examples 5, 68 and 9 of Aikawa; abstract, Examples 4, 5 and 8 of Kitaguchi).

Schmidt discloses that liposomes containing are useful in handling arteriosclerosis. The phospholipids, which could be used in making the liposomes, include PC and PS (abstract, col. 5, lines 24-34 and claim 4).

It would have been obvious to one of ordinary skill in the art to encapsulate or associate the benzimidazole derivatives of Aikawa (600) in liposomes since the references of Kitaguchi, and Aikawa each teach that the liposomes are selectively taken

up by vascular smooth muscle cells and macrophages and since the reference of Schmidt teaches that liposomes can be used in handling atherosclerosis and Mijalli suggests the liposomal delivery of benzimidazoles for the treatment of atherosclerosis. .

Applicant's arguments have been fully considered, but are moot in view of the new rejections. Applicant's arguments with regard to the unexpected results have already been addressed by the examiner.

The reference of Unger (5,088,499) which teaches that benzimidazoles are incorporated in the liposomal membranes is cited as interest (see col. 5, line 62 through col. 6, line 10).

Some of the references (crossed out) were not considered because these are in Japanese language and applicant has not stated their relevance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Krass Frederick can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gollamudi S Kishore/
Primary Examiner, Art Unit 1612

GSK